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August 31, 2017

In re Mylan N.V. Securities Litigation, No. 1:16-cv-07926 (JPO) (S.D.N.Y.)

Dear Judge Oetken:

I write, on behalf of Defendants in the above-titled action, to respond to Plaintiffs' letter to Your Honor of August 28, 2017 [Dkt. #53] (the "Letter"), in which Plaintiffs help themselves to extra briefing on Defendants' motion to dismiss in an effort to revive the deficient allegations in their consolidated amended complaint [Dkt. #39] (the "Complaint"). In their letter, Plaintiffs present for the Court's consideration, and mischaracterize the contents of, two press releases and an unadjudicated *qui tam* complaint. (See Exs. A-C to the Letter.)

Defendants do not object to the Court taking judicial notice of the three documents appended to Plaintiffs' Letter. In other words, the Court may take judicial notice of the fact that Mylan N.V. ("Mylan") and the U.S. Department of Justice (the "DOJ") each announced the completion of a settlement with respect to the Medicaid classification of EpiPen, and informed the public of information relevant to that agreement; and of the fact that allegations have been made in a *qui tam* complaint that has never been adjudicated.<sup>1</sup>

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<sup>1</sup> By contrast, it would be clearly inappropriate for this Court to grant Plaintiffs' request that it consider new legal arguments that appear nowhere in either Plaintiffs' 144-page Complaint or their 25-page brief in opposition to Defendants' motion to dismiss [Dkt. #49] (the "Opposition Brief"). For example, Plaintiffs now contend, for the first time, that Mylan executives knew that EpiPen was misclassified because "the Purported 1997 Letter ceased to apply to EpiPen as early as 2009", when Mylan was allegedly required to change certain National Drug Codes. (Letter at 4.) But this allegation is based on *no* new facts, was *never* pleaded in the Complaint, and is *not* contained in Plaintiffs' Opposition Brief or other papers. It should be disregarded. See *Jordan (Bermuda) Inv. Co. v. Hunter Green Invs. Ltd.*, 154 F. Supp. 2d 682, 690 (S.D.N.Y. 2001) (rejecting, on a motion to dismiss, plaintiff's "attempt to introduce evidence [and] legal arguments" contained in a different complaint that were not in the complaint before the court, even where plaintiff presented those new materials as part of its papers in opposition to a motion to dismiss);

If the Court takes judicial notice of these documents, they still provide no support for Plaintiffs' contention that the Complaint should not be dismissed, or that they should be granted leave to amend. (*See* Letter at 1, 5.) That is because the only way Plaintiffs can make that claim, and request that relief, is by radically mischaracterizing the contents of their new documents and by treating as fact unadjudicated allegations in a now-settled complaint. Given that the documents Plaintiffs identify do not support Plaintiffs' claims, and that Defendants' bases for dismissal apply with the same force to the new documents as they do to all of Plaintiffs' other baseless allegations, the Complaint should be dismissed with prejudice—and any amendment would be futile. *See Liana Carrier Ltd. v. Pure Biofuels Corp.*, 151 F. Supp. 3d 319, 324-25 (S.D.N.Y. 2015) (denying plaintiffs' letter request for leave to amend where "[p]laintiffs' proposed amendments to their [c]omplaint would be futile because they would not survive a motion to dismiss"), *aff'd in relevant part*, 672 F. App'x 85 (2d Cir. 2016).

With respect to Mylan's press release (Ex. A), Plaintiffs claim that it contains an "admi[ssion] that the EpiPen was misclassified" (Letter at 3). That is absolutely false. Mylan disclosed in the press release that "[t]he settlement does *not contain an admission or finding of wrongdoing*", and that EpiPen "has been classified with [the Centers for Medicare and Medicaid Services] as a non-innovator drug . . . *based on longstanding written guidance from the federal government*". (Ex. A (emphases added).) These same facts were set out in the press release Mylan issued last October, announcing the settlement in principle [Dkt. #47-2], which press release Plaintiffs have incorporated by reference into their Complaint (*see* Defs.' Opening Br. [Dkt. #46] at 3 n.2 (citing Compl. ¶¶ 85, 311 & n.57)). And, of course, there are many reasons why a company would enter into a settlement of this kind—including agreeing to change its practices and to make a monetary payment—even if it did not commit the alleged wrongdoing, including (as was stated in the press release) "'bringing closure to th[e] matter . . . to allow [the company] to move forward'". (Ex. A; *see* Defs.' Opening Br. at 17.)

With respect to the DOJ press release (Ex. B), Plaintiffs argue that it "makes clear that the DOJ had grounds, uncovered through its investigation, to allege that Mylan 'knowingly misclassified' the EpiPen". (Letter at 3 (alteration omitted).) But again, Plaintiffs ignore words they do not like, particularly the DOJ's express statement in the press release that "[t]he claims settled by this agreement are *allegations only*, and there has been *no determination of liability*." (Ex. B (emphases added).)

And, with respect to the *qui tam* complaint, it does not, as Plaintiffs argue, provide "*direct evidence*" of liability (Letter at 3) because the complaint was settled before ever having been adjudicated (*id.* at 1); *see Low v. Robb*, No. 11-cv-2321, 2012 WL 173472, at \*9 (S.D.N.Y. Jan. 20, 2012) ("It is well settled under Second Circuit

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*Weizmann Inst. of Sci. v. Neschis*, 229 F. Supp. 2d 234, 247 & n.21 (S.D.N.Y. 2002). In any event, the argument fails because the National Drug Code assigned to a product does not dictate its classification under the Medicaid rules; as Plaintiffs themselves concede, a drug's classification depends on whether the drug was "originally marketed under an original [NDA]". (Compl. ¶ 44 n.13 (citing 42 U.S.C. § 1396r-8(k)(7)).)

law that allegations in a complaint that are either based on, or rely on, complaints in other actions that have been dismissed, settled, or otherwise not resolved, are, as a matter of law, immaterial.” (internal quotation marks omitted)).

Defendants will further respond to Plaintiffs’ allegations in their reply brief on September 22, as agreed to by the parties and ordered by the Court in January [Dkt. #35]. In the meantime, I am available at the Court’s convenience should Your Honor have any questions relating to the foregoing.

Respectfully,



Sandra C. Goldstein

Hon. J. Paul Oetken  
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